510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K061065

B. Purpose for Submission:

Marketing in the U.S.

C. Measurand:

Human Hemoglobin

D. Type of Test:
Immunological test for the qualitative detection of monoclonal antibodies for human hemoglobin

E. Applicant:

TECO Diagnostics

F. Proprietary and Established Names:

Teco Rapid Fecal Occult Blood (FOB) Card Test

G. Regulatory Information:

1. Regulation section:

   21 CFR § 864.6550 Occult Blood Test

2. Classification:

   Class II

3. Product code:

   KHE

4. Panel:

   Hematology 81

H. Intended Use:

1. Intended use(s):

   Teco Rapid Fecal Occult Blood (FOB) Card Test is an immunochromatographic assay intended for the determination of human hemoglobin in feces by professional laboratories or physician's offices. It is useful to determine gastrointestinal bleeding founding a number of gastrointestinal disorders such as colorectal carcinoma, colon polyps, diverticulitis and ulcerative colitis.

2. Indication(s) for use:

   Teco Rapid Fecal Occult Blood (FOB) Card Test is recommended for use in 1) routine physical examination, 2) hospital monitoring for bleeding in patients, and 3 screening for colorectal cancer or gastrointestinal bleeding from any source.

3. Special conditions for use statement(s):

   N/A

4. Special instrument requirements:

   N/A

I. Device Description:

The Teco Rapid Fecal Occult Blood (FOB) Card Test is a sandwich immunoassay; it employs a combination of monoclonal and polyclonal antibodies to selectively identify human hemoglobin in test samples with a high degree of sensitivity. It consists of the test device and buffer in a sample collection tube.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Alfa Scientific, Inc. Instant-View™ Fecal Occult Blood Test

2. Predicate 510(k) number(s):

   K021423

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample	Feces in extraction buffer	Same
Intended Use	Qualitative detection of fecal occult blood in feces by professional laboratories and physician's offices	Same
Extraction Buffer	PBS	Same
Sensitivity	50 ng hHb/ml buffer	Same

Differences		
Item	Device	Predicate
Test Principle	Immunoassay utilizing monoclonal and polyclonal antibodies for the detection of human hemoglobin	Immunoassay utilizing monoclonal for the detection of human hemoglobin

K. Standard/Guidance Document Referenced (if applicable):

NCCLS EP9-A2 Method Comparison and Bias Estimation using Patient Samples; Approved Guideline

NCCLS EP2-P User Protocol for Evaluation of Qualitative Test performance; Approved Guideline

L. Test Principle:

The Teco Rapid Fecal Occult Blood Card Test employs polyclonal and monoclonal antibodies to detect human hemoglobin in feces. A fecal sample is collected and placed into the fecal collection tube containing a buffer solution. The resulting fluid with extracted hemoglobin (if any) is then added to the test device. The sample fluid mixes with anti-hemoglobin dye-conjugate in the test membrane forming an antigen-dye complex which migrates through the test device. The complex is captured in the test zone by immobilized anti-hemoglobin antibodies. The captured dye-complex becomes visible as a rose-pink band within the test zone, which indicates the test has detected human hemoglobin. In the absence of hemoglobin no line will form in the test zone.

A procedural control is built into the test device to indicate proper test performance. It appears as a rose-pink sandwich dye conjugate reaction and should appear regardless of the test result.

A rose-pink band in the test zone and in the control zone at or before five minutes is considered a positive result by the criteria of the test. A band only in the control zone at five minutes is a negative result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Fresh human hemoglobin free stool extraction specimens were spiked with human hemoglobin at three different concentrations: 0, 100, and 1000 ng/ml. Each specimen concentration was tested in each day for 20 days. There were 20 total replicates for each concentration specimen and the agreement was 100% at each concentration.

Reproducibility studies were also conducted at three physician office laboratories with 120 human hemoglobin free stool extracts separated into 4 groups. Each group of specimens was spiked with 0, 50, 60, and 1000 ng/ml of human hemoglobin. Tests were conducted by laboratory technicians with various degrees of educational background and experience and compared to the results of a professional user. There was 99.2% agreement between the results from site 1 and the professional user. There was 98.3% agreement between the results from site 2 and the professional user. There was 100% agreement between the results from site 3 and the professional user.

b. Linearity/assay reportable range:

N/A

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Internal Control: A procedural control is built into the test device to indicate proper test performance. It appears as a rose-pink sandwich dye conjugate reaction and should appear regardless of the test result.

External Control: Positive and negative controls should be run to insure that the captured and conjugated antibodies are present and reactive.

d. Detection limit:

The minimal detectable concentration of hHb is 50 ng/ml in buffer or 5ug/g in feces.

e. Analytical specificity:

This FOB test is specific to human hemoglobin. The following substances when spiked in both positive and negative specimens did not interfere with the test results.

Substance	Concentration (ug/ml)
Chicken Hb	500 ug/ml
Pork Hb	500 ug/ml
Horse Hb	500 ug/ml
Beef Hb	500 ug/ml
Rabbit Hb	500 ug/ml
Goat Hb	500 ug/ml
Horseradish Peroxidase	2000 ug/ml

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

The Teco Rapid FOB Card Test was compared to a predicate device with 120 human hemoglobin free feces extraction specimens in house. The specimens were divided into 6 groups containing 20 specimens. The six groups were spiked with human hemoglobin in the following concentrations: 0, 20, 40, 50, 100, and 2000 ng/ml. The specimens in each group were further divided into two groups: Group A was tested immediately while Group B was stored for 10 days at 2-8°C. The total agreement was 98.3%. The positive percent agreement was 96.3% and the negative percent agreement was 100%.

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

5. Expected values/Reference range:

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.